

REMARKS

Overview

Claims 1-74, 85 and 99-101 are pending in the present application. Claim 2 has been amended. The Applicants thank the Examiner for withdrawing the various rejections to claims 1-4, 34-65, 66, 67, 68-74, 85 and 99. The present response is an earnest effort to place all claims in proper form for immediate allowance. Reconsideration and passage to issuance is therefore respectfully requested.

New Grounds of Rejection and Claim Rejections Maintained

Claim 2 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 has been amended to clarify that a "cell comprising a nucleic acid sequence encoding an $\alpha(1,3)$ galactosyltransferase protein" is used in the invention. The Applicants wish to thank the Examiner for bringing this to our attention and request that this rejection be withdrawn.

Claim Rejections Under 35 U.S.C. § 103

Claims 1-4, 34, 67, 85 and 99 are rejected under 35 U.S.C. § 103(a) as being obvious over LaTemple-II (LaTemple II, D.C. et al, Cancer Research, 56:3069-3074, 1996, cited in IDS; referred to as LaTemple-II to distinguish from LaTemple published in 1999, cited in a previous Office Action), in view of Link Jr. (Link, Jr. et al., US 7,005,126 B1 issued 2/28/2006, effective filing date 6/8/1999) and further in view of ATCC (ATCC Cell Lines and Hybridomas, 8th edition, 1994, page 100; of record).

The Examiner states that LaTemple-II teaches the concept of irradiated tumor cell lines transfected with an $\alpha(1,3)$ galactosyltransferase (α -1,3GT) encoding polynucleotide sequence, and its use as a tumor therapeutic composition. The Examiner further states that Link, Jr. teaches a truncated version of the murine α -1,3GT gene which may be SEQ ID No: 1. Finally, the Examiner states that the ATCC catalog teaches the use of A549 cells.

A) Link, Jr. is improper prior art under 35 U.S.C. § 103(c).

Reconsideration and allowance of the claims as filed is requested. In view of the evidence here submitted, Link Jr. cited by the Examiner does not qualify as prior art for use in a 35 U.S.C. 103(a) rejection. 35 U.S.C. § 103(c)(1) states:

Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Link, Jr. only classifies as art under 35 U.S.C. § 102(e) and because Applicant's invention was developed by another, under obligation of assignment at the time of invention to the same entity as Link Jr., it may not be used as art against the Applicant.

i. Applicant's invention was developed "by another" as outlined in the MPEP

If the named inventors between an application and a granted patent are not exactly the same, the inventive entity is to be considered "by another". MPEP § 2136.04 ("The fact that the application and reference have one or more inventors in common is immaterial.") Applicant's invention is considered to be developed "by another" because not all inventors are the same. Link Jr. names Charles J. Link, Jr. and Tatiana Seregina as the inventors, while the Applicant

currently lists three individuals, Charles J. Link, Jr., Tatiana Seregina and Gabriela Rossi. The presence of Rossi makes this invention made "by another" according to the MPEP.

ii. Link Jr. only qualifies as prior art under 35 U.S.C. 102(e)

Link Jr. fails to qualify as art under both 35 U.S.C. § 102(a) and § 102(b). No evidence is provided which shows the invention was known or used prior to Applicant's invention.

Likewise, Link Jr. was not issued until February 28, 2006, so it was not patented prior to Applicant's invention (which was provisionally filed on October 9, 2002). Thus, the '126 patent cannot classify as art under § 102(a). Also, Link Jr. was not patented for more than one year from the Applicant's invention, nor was it printed in a publication. Therefore, it is also disqualified as art according to § 102(b).

However, Link Jr. does qualify as art under § 102(e). 35 U.S.C. § 102(e)(2) defines prior art as "a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent". Here, Link Jr. was issued on February 28, 2006 claiming priority to a provisional filed on June 8, 1999. As mentioned above, Applicant's priority date is October 9, 2002, which is after the allowance of Link Jr.. Thus, Link Jr. only qualifies as art according to § 102(e).

iii. Obligation of assignment to the same entity

Application 10/682,178 and Patent 7,005,126 B1 were, at the time the invention of Application 10/682,178 was made, under obligation of assignment to Iowa Health System. Application 10/682,178 was under an obligation of assignment at the time the invention was made to Iowa Health System. Accordingly, Application 10/682,178 has been assigned to Iowa Health System. (See Assignment made to the United States Patent and Trademark Office at Reel 014668, Frame 0969). Patent 7,005,126 B1 is assigned to the Human Gene Therapy Research

Institute. The Human Gene Therapy Research Institute is wholly owned (100%) by Central Iowa Health System. (See enclosed document titled *License Between Central Iowa Health System and NewLink Genetics Corporation*, Page 1 (unnumbered), first paragraph under RECITALS heading). Central Iowa Health System is a wholly controlled (100%) subsidiary of the not for profit Iowa Health System. (See attached document titled *Appendix A*; page A-1, second paragraph; and page A-2, flow chart). Thus, Iowa Health System is the parent company of Human Gene Therapy Research Institute. Therefore, at the time of invention, Application 10/682,178 and Patent 7,005,126 B1 were under obligation of assignment to the same company, Iowa Health System. See MPEP § 706.02(I)(2); Example 1 ("Parent Company owns 100% of Subsidiaries A and B - inventions of A and B are commonly owned by the Parent Company."). As a result, Link Jr. is disqualified as prior art for this application.

B) LaTemple-II teaches away from the use of cell lines and allogeneic vaccines.

The claims of the invention specifically require that the cells be derived from "whole human tumor cell lines." As a result, the vaccines made by the present invention are allogeneic vaccines—meaning that they come from a source other than the patient to be treated. Although tumor lines were used in the reference, LaTemple-II specifically teaches the use of autologous vaccines in cancer prevention. (LaTemple-II lines 21-23 page 3069.) In fact, LaTemple-II specifically teaches that "many human TAAs have not yet been identified" making autologous tumor cells "a potential source for vaccine against the developing tumor." (LaTemple-II lines 21-23 page 3069.) A review of LaTemple-II in its entirety shows that the use of allogeneic tumor vaccines is clearly not contemplated by the author. (See *e.g.* LaTemple-II lines 21-23 page 3069, lines 46-51 page 3073.) Tumor cell lines, such as those mentioned in claim 1, are cell lines that have been cultivated and passaged many times and the identity of the original donor is frequently

unknown (such as the ATCC cell lines cited by the Examiner). As a result, LaTemple-II certainly does not teach the use of human tumor cell lines in the present invention and actually teaches away from any such use. Additionally, LaTemple-II shows that any success observed with the present invention are results which are unexpected by a person skilled in the art.

C) There is no guidance or suggestion to select A549 cells from the many cells described in the ATCC catalog.

The Examiner states that it would be obvious to one skilled in the art to select A549 cells, however, no reason is given as to why one skilled in the art would select that particular cell line. Although KSR v. Teleflex states that inventions may be obvious when "there are a finite number of identified, predictable solutions" it also states that the Examiners "analysis should be made explicit." KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1741, 1742 (U.S. 2007). Although the ATCC catalog is not technically infinite it lists a considerably large (and certainly not finite) number of cell line combinations. The Examiner fails to explicitly state the reason as to why a person skilled in the art would chose A549 from the many other options.

Because the 103(a) rejection of claims 1-4, 34, 67, 85, and 99 over LaTemple-II, Link Jr., and ATCC utilize improper prior art (Link Jr.), prior art which teaches away from the present invention (LaTemple-II), and fails to explicitly state the reason for selecting a particular combination from an extremely large number of alternatives (ATCC), the Applicants respectfully request that the rejection be withdrawn.

Claims 1-4, 34, 66, 67, 85 and 99 are rejected under 35 U.S.C. § 103(a) as being obvious over LaTemple-II (LaTemple II, D.C. et al, Cancer Research, 56:3069-3074, 1996, cited in IDS) in view of Link, Jr. (Link, Jr. et al., US 7,005,126 B1; issued 2/28/2006; effective filing date

6/8/1999) and further in view of ATCC (ATCC Cell Lines and Hybridomas, 8th edition, 1994, page 100; of record), and further in view of Berd (US 6,333,028 issued 12/25/2001, effective filing 8/14/1998, of record).

The Examiner cites LaTemple-II, Link Jr., and ATCC for the same reasons as above. Berd is cited to support the use of adjuvants in the vaccine. The reasoning regarding LaTemple-II, Link Jr., and ATCC stated above applies to the present rejection as well. Berd does not solve any of these deficiencies. As a result, the 103(a) rejection is improper for the reasons stated above. The Applicants respectfully request that this rejection be withdrawn.

Claims 1-4, 34, 67, 85 and 99-101 are rejected under 35 U.S.C. § 103(a) as being obvious over LaTemple-II (LaTemple II, D.C. et al, Cancer Research, 56:3069-3074, 1996, cited in IDS; referred to as LaTemple-II to distinguish from LaTemple published in 1999, cited in a previous Office Action), in view of Link, Jr. (Link, Jr. et al., US 7,005,126 B1 issued 2/28/2006, effective filing date 6/8/1999) and further in view of ATCC (ATCC Cell Lines and Hybridomas, 8th edition, 1994, page 100; of record), and further in view of Pardoll (US 6,187,306, 2/13/2001, effective filing date of 8/16/1996).

The Examiner cites LaTemple-II, Link Jr., and ATCC for the same reasons as above. Pardoll is cited to support the use of multiple cell lines in the vaccine. The reasoning regarding LaTemple-II, Link Jr., and ATCC stated above applies to the present rejection as well. Pardoll does not solve any of these deficiencies. As a result, the 103(a) rejection is improper for the reasons stated above. The Applicants respectfully request that this rejection be withdrawn.

Double Patenting

Claims 1-5, 66, 67, 68, 85 and 99-101 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 11/013,685.

The Applicants would be pleased to submit a terminal disclaimer upon notice that the pending claims are allowable.

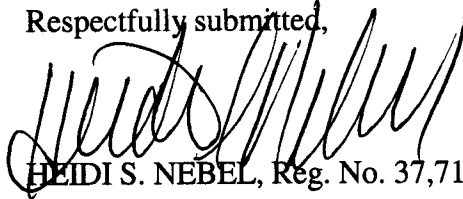
Conclusion

This is a request to extend the period for filing a response in the above-identified application for one month from July 29, 2008 to August 29, 2008. Applicant is a small entity; therefore, please charge Deposit Account number 26-0084 in the amount of \$60.00 to cover the cost of the one month extension. Any deficiency or overpayment should be charged or credited to Deposit Account 26-0084.

No other fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Heidi S. Nebel", written over the typed name.

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Enclosures